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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,751	08/07/2000	BERTIL R.R. PERSSON	U012883-2	9637
7590 08/17/2004 LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			EXAMINER OROPEZA, FRANCES P	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 08/17/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/601,751	Applicant(s) PERSSON ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/10/04 (Election and Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65-69, 71-73, 75, 77-79 and 81 is/are allowed.
- 6) ☒ Claim(s) 42-64, 70, 74, 76 and 80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 10/27/03 has been entered.

Response to Restriction

2. The Applicant's regarding the restriction requirements and newly submitted claims have been fully considered and they are convincing. Claims 42-81 are now being prosecuted in this application.

Claim Rejections - 35 USC § 112

3. Claims 74 and 80 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment substance (therapeutic substance, genetic material and ionizing radiation) is introduced by a coated electrode (specification – page 12, line 14-190, does not reasonably provide enablement for “wherein the treatment substance is introduced by injection”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The apparatus or method associated with the injection can not be found in the specification.

Claim Rejections - 35 USC § 103

4. Claims 42-55, 57-59, 61-64, 69, 70 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (US 6208893) in view of Klieck et al. (US 5370645).

Hofmann discloses an electroporation apparatus comprising a high voltage pulse generator (12) and a connective electrode template for use with interstitial tumors (col. 1 @ 66 – col. 2 @ 9), the apparatus comprising electrodes that are needles (claim 61), insulating the electrodes (claim 62), fixing the electrodes with a fixture (claim 63), and providing holes in the fixture (claim 64) (abstract; figure 1; col. 2 @ 10-23; col. 4 @ 42-49; col. 4 @ 63 – col. 5 @ 28; col. 7 @ 46-58; col. 8 @ 45-54; col. 9 @ 8-15; col. 10 @ 1-4; col. 11 @ 46-53).

As discussed in the previous paragraph Hofmann disclose the claimed invention except for an impedance measuring unit used to modulate the high voltage generator by way to the registration and conversion device.

Klieck et al. teach medical device control using an impedance measuring and feedback system for the purpose of regulating the pulse energy. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an impedance monitoring and feedback system in the Hofmann system in order to avoid tissue damage (abstract; col. 3 @ 63 – col. 4 @ 9; col. 4 @ 61- col. 5 @ 2; col. 6 @ 5-28).

It is noted the “to generate”, “ to measure”, “to receive...” limitations of the apparatus claims amount to intended use limitations of which modified Hofmann performs of is inherently capable of performing.

5. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (US 6208893) in view of Klieck et al. (US 5370645) and further in view of Eggers et al. (US 5928159). As discussed in paragraph 4 of this action, modified Hoffman discloses the claimed invention except for sensors detecting the distance between electrodes and the control unit adjusting the electrode voltage based on the distance.

Eggers et al. disclose an apparatus for characterizing and treating tumors and teach that it is known to use sensors to detect the distance between electrodes and to enable the control unit to adjust the electrode voltage based on the distance (col. 6 @ 20-64). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified Hofmann system, with the sensors to measure distance between the electrodes and to enable the control unit to provide therapy based on the distance measurements as taught by Eggers to enable interstitial tumors to be more accurately monitored so the treatment parameters can be optimally varied to provided effective treatment for the tumor (col. 5 @ 25-36).

6. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (US 6208893) in view of Klieck et al. (US 5370645) and further in view of Mawad (US 6428462). As discussed in paragraph 4 of this action, modified Hofmann discloses the claimed invention except for the electrode consisting of radioactive material.

Mawad discloses a radiotherapy implant and teaches that it is known to use an electrode with a radioactive device to enable placement of radiation near the tumor (col. 3 @ 34-37; col. 5 @ 21-49). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified Hofmann system, with the radioactive

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therapy implant as taught by Mawad to provide radiotherapy for a patient where combined chemotherapy and radiation therapy is the recommended treatment (col. 1 @ 20-25).

Allowable Subject Matter

6. Claims 65-68, 71-73, 75, 77-79 and 81 are allowed.

Statutory Basis

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

8/5/04
JPO

Angela D. Sykes

ANGELA D. SYKES
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